



EQUIPMENT QUALIFICATION

Document No.

USER REQUIREMENT SPECIFICATION

Revision No.

00

Equipment Name

HEATING, VENTILATION AND AIR
CONDITIONING (HVAC) SYSTEM

PAGE No.

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USER REQUIREMENT SPECIFICATIONS

HEATING, VENTILATION AND AIR CONDITIONING (HVAC)

Document Reference: Nil

Issue Date: Nil

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Approval:

This document has been developed and the individuals listed below have reviewed the document and agree with its content and with their signature grant approval for its execution.

<i>Functional area</i>	<i>Name</i>	<i>Designation</i>	<i>Signature</i>	Date
PREPARED BY				
User Department				
REVIEWED BY				
User Dept. Head				
Engineering Dept. Head				
Environment, health and safety				
Quality Control (if applicable)				
Quality Assurance				
APPROVED BY				
QA Head				
Plant Head				

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- 1.0 Objective:** The objective of this document is to provide the requirement and appropriate design to support the prospective supplier to identify company needs, price quote for the Heating, ventilation and air conditioning system (HVAC) and performance requirements for procurement of HVAC system including major ancillary component or fabrication of the area so as to meet the in-house requirements as well as compliance with cGMP.

The supplier shall abide by the information and conditions set forth by this document as well as the standard purchasing terms and conditions of company.

- 2.0 Scope:** This user requirement specification (URS) is applicable for the procurement of Heating, ventilation and air conditioning system.

- 3.0 Reason for URS:** To procure Heating, ventilation and air conditioning system for installation in service area, which will supply to Sampling area-I, Material airlock and Man Airlock for achieving the required area grade and maintaining the area environmental conditions.

The reason for preparing this document is:

Please tick any one (or multiple) option(s) from the following):

New or refurbished premises/equipment

Purchase of Utility Systems

Change in Design of Equipment

In-Use Systems that don't have a URS

Others (Specify)

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4.0 Responsibility: Personnel involved in qualification activity.

Department	Name	Activity
User		To provide the User Requirement Specification (URS)
Engineering		To provide requirements with respect to utilities, components, based on the location of use and desired HVAC parameters
Health Safety and Environment		To provide the safety requirements of HVAC and facility
Quality Assurance		To be a part of qualification team
QA Head		To review and approve the requirement and Qualification document
Plant Head		To review and approve the requirement and Qualification document

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5.0 Equipment Description:**Air Handling Unit:**

The air-handling unit serves to condition the air and provide the required air movement within the area.

Lower plenum:

The lower plenum shall be fitted on the bottom side of the area.

Ducting:

Supply ducting: This duct shall be provided between lower plenum and the supply air opening of Air handling unit.

Return ducting: This duct shall be used for conveying the air through return riser to blower section. Then the air shall be circulated through the blower.

6.0 Information of Input Materials: 10-20% fresh air is taken from service floor and 80-90% of Re-circulated air taken from Sampling Area-I, Material Airlock and Man Airlock.

7.0 Information of Output Materials: Filtered Air provide to the Sampling Area-I, Material Airlock and Man Airlock area.

8.0 Environment: This section gives a brief summary of the layout and physical condition of the proposed site of the HVAC system. This includes (but not limited to), the data sheet of the room where proposed equipment is to be placed with proposed placement drawing showing room dimensions, Design of rooms to be maintained by the HVAC system, access route from outside, HVAC supply/return grill locations, utility point locations, etc.

S.No.	Parameter	Specifications/Dimension
1.	Temperature to be maintained in the area	NMT 25 °C
2.	Relative Humidity to be maintained in the area	NMT 60%

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9.0 Equipment Design and Principle of Working:

The unit shall consist of Filter section, single Blower section, Heat exchanger section.

10.0 Process Description: This section mentions in brief the details of the process to be handled by the equipment.

11.1 The air-handling unit (AHU) will have facility for once through system where 10-20% fresh air is taken from service floor and 80-90% of Re-circulated air for re circulation for Sampling Area-I, Material Airlock and Man Airlock area.

11.2 The filtered air shall be passed through a cooling coil where chilled water is supplied at 8 to 13 °C to cool the air to attain the dew point for removal of moisture. The cold air which comes out of the coil will pass through heater coils or warm water coil where the incoming cold air will be heated to maintain the room temperature of NMT 25 °C. This air will then pass through a set of filters and dehumidifier before entering the rooms.

11.3 Dust collectors of adequate capacity shall be provided for areas of high dust generation. The system is designed for high velocity dust collection points with adequate filter provided for capturing the dust. The exhaust from the dust collectors shall be re-circulated to the AHU through EU 13 final filters.

Pressure differential across the rooms shall be designed in a way so as to maintain minimum required pressure differential even when the dust collector is not in operation.

11.0 Functional Requirements of HVAC System:

12.1 Functionality of the HVAC System: The desired functional requirements and how it shall operate are listed under this section.

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S. No.	Parameter	Specifications
1.	Design	CFM : 1650
2.	Electrical motor for main supply blower	Motor should be compatible to run with VFD
3.	Process fan detail	Fan Type : Backward (PLUG-315) Motor type : Foot Mount/ Flame Proof
4.	Rates of air changes per hour in cubicle	Should be NLT 20 air changes per hour for ISO class 8 area at rest condition.
5.	Particulate matter count	Should meet the specifications of Area Class ISO 8 / Grade D.
6.	Microbial load	Should meet the specifications of Class ISO 8/ Grade D: By Settle plate method: NMT 100 CFU/plate. By Air sampling method: NMT 200 CFU/m ³
7.	Recovery / Clean up period	Should be achieved within 15 minutes.
8.	Recovery for temperature and RH	Should be achieved within 30 minutes.
9.	Air flow pattern	The smoke should be diffused uniformly at supply air location to room and pass through return location. Also smoke should be passed from positive air pressure area to negative air pressure area.



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S. No.	Parameter	Specifications
10.	Filter Detail	<p>Fresh Air filter: Shall be provided</p> <p>Pre filter: Shall be provided</p> <p>Fine Filter: Shall be provided</p> <p>HEPA Filter: Shall be provided</p>
12.	Chilled Water Coil	Type: Cooling coil
13.	Hot Water Coil	Type: Hot water Coil
14.	Valve control(if applicable)	Controller and sensor should be provided after coil or in the area for actuation of chilled water control valve.
15.	Valves and strainers	<p>Isolation valve should be provided at chilled water inlet and outlet.</p> <p>Two way actuator mixing valve control valve for chilled water and two way for hot water should be provided.</p> <p>Strainer should be provided at Chilled water inlet line.</p> <p>Pressure gauge isolation valve should be provided.</p>
16.	Ducting	<p>Return air ducting: Shall be provided</p> <p>Supply air ducting : Shall be provided</p> <p>All duct joints should be filled with sealant for zero leakages.</p> <p>Volume control dampers should be used for the better air control.</p> <p>Neoprene rubber gasket should be used between duct joints.</p>



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S. No.	Parameter	Specifications
		Individual damper for each supply and return of the room side should be provided.
17.	VFD for supply blower	Suitable capacity of VFD to be provided.
18.	Pipelines	Chilled water lines: Shall be provided
		Insulation: Shall be provided on chilled water lines
		Warm water line: Shall be provided
		Insulation: Shall be provided on warm water lines
	Condensate drain line: Shall be provided	
19.	Operational feature	AHU should be operational through Auto / Manual switch and also compatible to run with VFD.
20.	Fresh air	Minimum 10 - 20%
21.	Relief air (if applicable)	Not more than 8-10%
22.	Filter section	All the filter banks, blower section, coil section should have the provision for the measurement of the differential pressure across the filters.
23.	Damper section	Low leakage aerofoil dampers should be provided.
		Individual damper should be provided for supply, return, fresh air, relief air etc.
		All dampers should have positive locking arrangement.

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12.2 Instrumentation Requirements: This section mentions in brief the minimum requirement for measuring instrumentation for controlling and monitoring of process parameters. e.g. magnehelic gauge / manometer and etc.

S.No.	Parameter	Specifications
1.	Differential magnehelic gauge / manometer if applicable	Magnehelic manometer should be provided across HEPA / Fine filter bank.
		Manometer should have proper zero setting.

12.3 Data Collection and Reporting: This section mentions in brief the data that is expected from the equipment with the respective unit of measurement. Need for printouts are also mentioned, if applicable e.g. temperature, RPM, pressure, etc.

S.No.	Parameter	Specifications
1.	Temperature	➤ In °C
2.	Pressure	➤ In MMWC or Pascal (as applicable)

13.0 Performance Features: The parameters that are planned to be evaluated during performance qualification and validation activities are mentioned.

S.No.	Parameter	Specifications
1.	Performance of the system according to operation.	The system is intended to be operated regularly 24 hours, 7 days per week.
2.	Cleaning requirements	Easy accessible for cleaning of parts and should be provided with quick fixing arrangement.

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14.0 Capacity / Speed: The desired capacity with the UOM is specified in this section.

S.No.	Parameter	Specifications
1.	Capacity	1650 CFM

15.0 Automation and Safety Features: The minimum required as well as desired automation and safety features (alarms, interlocking, etc.) are listed in this section.

S.No.	Parameter	Specifications
1.	Noise level	Should be not more than 80 dB in 01 meter distance.
2.	Safety guards	Safety guards should be provided to all moving parts.
3.	Limit switch	Limit Switch should be provided for service door.
4.	Earthing connections	Proper earthing to be provided.
5.	View lamp and view window	Wether proof light should be provided in blower section with view glass on panel.
8.	Alarm system	Alarm should be provided.
9.	Emergency stop	The system shall have an Emergency stop mechanism.
10.	Power failure and recovery	The system should not function in case of power failure and starts in auto mode or only after operator intervention.

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16.0 System Boundaries: Nil**17.0 Material of Construction:** Specifications for material of construction of HVAC system parts, are listed here.

S.No.	Parameter	Specifications
1	AHU Frame	Extruded Al Profile (thermal break)
2	AHU Panel	Double Skin
3	Frame work	Aluminium
4	Unit Base	G.S.S.
5	Process blower	Mild Steel powder coated
6	Ducting	Galvanized iron
7	Damper	Aluminium anodized
8	Chilled water line	Mild steel
9	Hot water line	Mild steel
10	Control panel	MS sheet with powder coated/ pre-wired electrical

18.0 Surface Finish: Specifications for surface finish of HVAC system parts are listed here.

S.No.	Parameter	Specifications
1.	Surface of air contact part	There should be no welding burrs. Surface should be smooth without crevices. All joints should be finished with silicon sealant and there should not be any gap for dust accumulating in the joints.

19.0 Electrical and Control Equipment Philosophy: A brief detail of the control requirements and whether the equipment is to be controlled using electrical system/



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microprocessor/ PLC/ computers or a combination of these are mentioned in this section.

The electrical system of the equipment shall be housed as per the cGMP and cGEP.

S.No.	Parameter	Specifications
1.	Operating panel	<ul style="list-style-type: none">➤ Control ON/OFF button➤ Emergency stop button
2.	Control panel	<ul style="list-style-type: none">➤ All switch gear items are enclosed

20.0 cGxP Considerations: The requirements for electronic compliance of the HVAC system in case of BMS.

S.No.	Parameter	Specifications
1.	Password protection (if applicable)	Three Level Security should be provided (Operator, Officer and Admin)
2.	Password (if applicable)	Password entries must be obscured (e.g. "*****").
3.	Quality of password (if applicable)	For password at least 4 characters required to enforce their use.
4.	Password protection (if applicable)	Three Level Security should be provided (Operator, Officer and Admin)
5.	Password (if applicable)	Password entries must be obscured (e.g. "*****")
6.	Quality of password (if applicable)	For password at least 4 characters required to enforce their use.

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S.No.	Parameter	Specifications
7.	Software (if any)	Software if any shall be 21 CFR part 11 compliance.

21.0 Expected Documents and Drawings: Requirement of documents to be delivered by the suppliers during the procurement life cycle. A suggestive list (but not limited to), is as listed below:

S.No.	Document details	Required (✓ / ×)
1.	Design Specification	✓
2.	Functional Specification	✓
3.	Instrument Listing	✓
4.	Machine Assembly Drawings	✓
5.	Bill of Material	✓
6.	Operator, Maintenance and Service Manual	✓
7.	Spare Parts List	✓
8.	MOC certificates	✓
9.	Calibration certificates of instruments	✓
10.	Test certificates of components/test devices	✓
11.	GA drawing	✓
12.	Electrical drawings	✓

✓: Applicable & required × : Not applicable

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22.0 Available Utilities:

S.No.	Parameter	Specifications
1.	Electricity	Electricity: Three phase
2.	Chilled water	Temperature: 8 to 13°C
3.	Warm water	Temperature 30 to 45°C

23.0 Maintenance Requirements: Maintenance related requirements like accessibility for easy maintenance, required spares, etc. are listed here.

S.No.	Parameter	Specifications
1.	Maintenance requirements	Easy accessible for Maintenance of parts and should be provided with quick fixing arrangement.
2.	Spare parts	List of Spare parts to be provided.

24.0 Delivery, Installation and Commissioning Requirements:

24.1 Should be delivered in disassembled condition and to be assembled at the site by the manufacturer/supplier service engineer.

24.2 Manufacturer should provide support in case of problems, which may not be able to rectify at the user end.

24.3 FAT if any required by the customer then, same to be performed jointly by the nominated persons from both the side at the manufacturer's site.

24.4 The manufacturer should install, qualify and commission the HVAC System at the user site and provide the necessary training to the user for operation and cleaning. Training to be provided by the manufacturer for the necessary critical steps involved in the operation, cleaning, maintenance, safety and handling of HVAC System.

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25.0 Other Specific Requirements: To provide the necessary servicing at the site at defined intervals. Language requirements in manual should be in English.

26.0 Reference Documents: Nil.

27.0 Abbreviations: Full forms of all abbreviations are listed here.

Abbreviation**Full form**

cGMP	: Current Good Manufacturing Practice
CFM	: Cubic Feet Per Minute
dB	: Decibel
EU	: European Unit
FLP	: Flame proof
HEPA	: High Efficiency Particulate Air
HVAC	: Heating, Ventilation and Air Conditioning
ISO	: International Organization for Standardization
MOC	: Material Of Construction
MM	: Microbial Method
Mm of WC	: Millimeter of Water column
MS	: Mild Steel
NFLP	: Non-flame proof
P & ID	: Process and Instrumentation Diagram
PUF	: Poly Urethane Foam
RH	: Relative Humidity
SWG	: Steel wire gauge
URS	: User Requirement Specification
VFD	: Variable Frequency Drive
"/ cm ²	: Inch per Centimeter Square
μ	: Micron

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28.0 Attachments: This section contains a list of all attachments referenced in the protocol.

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1.		
2.		
3.		
4.		
5.		